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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,844	03/04/2004	Peter G. Zaphiropoulos	2921-0145P	5375

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EXAMINER	
SANG, HONG	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
09/06/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/791,844	ZAPHIROPOULOS ET AL.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-18* is/are pending in the application.

4a) Of the above claim(s) *6-12 and 14-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5, and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: Zaphiropoulos et al.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/10/2007 has been entered.

2. Claims 1, and 5-18 are pending. Claims 2-4 are cancelled. Claims 6-12 and 14-18 are withdrawn from further consideration.

3. Claims 1, 5 and 13 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 101 & 35 USC § 112, 1st paragraph

4. The rejection of claims 1, 5 and 13 under 35 U.S.C.101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility is maintained.

The response states that the specification has shown the involvement of the novel human patched protein (PTCH2) in PTCH/SHH cascade of signaling events (see paragraphs [0081]-[0083]). The response states that a list of the scientific publications

on PTCH2 by the inventors and others provided evidence of a credible utility of the present invention.

Applicants' arguments have been carefully considered but are not found persuasive. The paragraphs [0081]-[0083] have been carefully reviewed but are insufficient to overcome the rejection. In the applicant's list of the scientific publications on PTCH2, only one is prior to the instant filing date (Motoyama et al., Nat Genet. 1998, 18(2): 104-6), which describes a mouse PTCH2 gene. Motoyama et al. teach that while PTCH and PTCH2 might have unique roles in epidermal development and Shh signaling, the functional role of PTCH2 remains to be examined (see page 106, 2nd column, 3rd paragraph). Motoyama et al. do not teach the expression and function of the mouse PTCH2 protein. The specification discloses that the mouse and zebrafish homologs of PTCH2 have been reported to be expressed in a partly overlapping pattern with PTCH1 during embryonic development and to be induced by SHH (see paragraph [0082], lines 1-2). The specification discloses that in BCCs having frequent mutations in the PTCH1 gene, the expression of the PTCH2 mRNAs is upregulated (see paragraph [0083], lines 1-2). As indicated in the previous office actions, while the instant PTCH2 (SEQ ID NO.1) is 57% identical to PTCH1, and 91% identical to the mouse PTCH2 sequence (see specification, page 12, lines 23-24), one of skill in the art cannot extrapolate the sequence homology data to the function of the PTCH2 protein, how the instantly claimed protein correlates to the human disease because the protein chemistry is highly unpredictable. It is known in the art that the relationship between the amino acid sequence of a protein (polypeptide) and its tertiary structure (i.e. its binding activity)

are not well understood and are not predictable. Furthermore, the specification discloses that whether PTCH2 may block the constitutive signaling of SMO, or could act as an additional SHH receptor, possible dependent on alternative splicing, remains as the subject of further experiment (see paragraph [0084]). Therefore, the exact function and how the PTCH2 protein is involved in the PTCH/SHH signaling pathway were not clear at the time of the filing of the instant application. The specification asserted specific utility for the claimed PTCH2, i.e. used in the pharmaceutical industry, e.g. treating cancer such as BCCs (see page 18, lines 3-4). While the specification teaches that PTCH2 mRNA expression is upregulated in BCCs, there is no indication that the PTCH2 protein expression is associated with BCCs. Furthermore, while PTCH2 gene is located to a chromosomal region often lost in tumors, even if the PTCH2 gene could be used for diagnosis of cancer, one skilled in the art still cannot conclude that the protein would be useful for treatment of cancer without the data showing that the PTCH2 protein is indeed expressed in the corresponding normal cells.

5. The rejection of claims 1, 5 and 13 under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention is maintained.

The rejection is maintained for the same reasons set forth above (see paragraph 4).

Claim Rejections - 35 USC § 112, 1st paragraph

6. The rejection of claims 1, 5 and 13 under 35 U.S.C. 1 12, first paragraph, as failing to comply with the enablement requirement is maintained.

Applicants presented the same argument as set forth in utility rejection (see paragraph 4).

Applicants' arguments have been carefully considered but are not found persuasive. In the applicant's list of the scientific publications on PTCH2, only one is prior to the instant filing date (Motoyama et al., Nat Genet. 1998, 18(2): 104-6), which describes a mouse PTCH2 gene. Motoyama et al. teach that while PTCH and PTCH2 might have unique roles in epidermal development and Shh signaling, the functional role of PTCH2 remains to be examined (see page 106, 2nd column, 3rd paragraph). Motoyama et al. do not teach the expression and function of the mouse PTCH2 protein. Based on the observation of the overexpression of PTCH2 mRNA in BCC, the specification asserts that the PTCH2 protein can be used for treating cancer such as BCC. As indicated in the previous office action, in the absence of a correlation between the claimed proteins and any diseases, such as cancer, the information obtained from over expression of the mRNA of PTCH2 in BCC only serves as the basis for further research on the observation itself. Therefore, absent evidence of the protein's expression including a correlation to any diseased state, one of skill in the art would not be able to predictably use the claimed proteins for treating any diseases including BCCs without undue experimentation.

Conclusion

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang, Ph.D.
Art Unit 1643
Aug. 27, 2007

/Christopher Yaen/
Primary Examiner
Art Unit 1643
August 29, 2007